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Gary Miller, Remedial Project Manager
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Superfund Division (6SF-RA)
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Subject: **Selection of the Relative Bioavailability Adjustment Factor for the Baseline Human Health Risk Assessment**
San Jacinto River Waste Pits Remedial Investigation/Feasibility Study
CERCLA Docket No. 06-03-10

Dear Gary:

The exposure analysis that was conducted to support the baseline human health risk assessment (HHRA) for the San Jacinto River Waste Pits (SJRWP) remedial investigation and feasibility study (RI/FS) employs a number of exposure parameters, many of which are provided in U.S. Environmental Protection Agency (USEPA) guidance, and others that are derived from information in the peer-reviewed literature. For the SJRWP HHRA, exposure assumptions include a relative bioavailability adjustment ($RBA_{soil\text{-}sediment}$) factor to account for the difference between the absorption of dioxins and furans from soil or sediment and absorption from the exposure medium in the study from which the 2,3,7,8-tetrachlorinated dibenzo-*p*-dioxin (TCDD) toxicity criterion was derived. A discussion of this exposure parameter and its technical basis was provided in the approved baseline HHRA (Section 5.1.2.2.2; Integral and Anchor QEA 2013) and was also presented in the approved exposure assessment memorandum (EA memo; Integral 2012). In response to your recent request, this letter provides additional detail on the technical foundations of the dioxin $RBA_{soil\text{-}sediment}$ used in the HHRA for the SJRWP, and addresses key points discussed in USEPA's recently developed framework for RBA factors for dioxins and furans.

When the EA memo and HHRA were prepared, Integral Consulting Inc. (Integral) cited USEPA (2010a), *Final Report on Bioavailability of Dioxins and Dioxin-Like Compounds in Soil*. USEPA (2010a) presents a thorough review and synthesis of RBA data provided in nine studies, six of which were used by USEPA to calculate RBA factors. These studies reported RBA test results for TCDD and other congeners in soil and sediment at concentrations

ranging from 1.9 to 2,300 pg/kg. Bioavailability factors for TCDD, in various test species, ranged from less than 0.01 to 0.49 (i.e., <1–49 percent). The arithmetic average of the mean bioavailability factors from each of these studies was 0.23 (i.e., 23 percent). This value was divided by the absorbed fraction of 0.50 (i.e., 50 percent)[1] used in establishing the toxicity criteria for dioxin-like compounds in the baseline HHRA, to derive the $RBA_{soil\text{-}sediment}$ of 0.46, rounded up to 0.50.

Since the time the HHRA for the SJRWP was finalized (May 2013), USEPA has published the *Soil Dioxin Relative Bioavailability Assay Evaluation Framework* (USEPA 2013). This document presents design parameter requirements for completing an assay to provide the basis for developing an RBA factor for use in risk assessment. Because USEPA (2010a) provides a detailed review of each relevant publication, I will not repeat those details here, and refer you to that report. However, Integral has completed a review of each paper addressed by USEPA (2010a) to see how each one compares to the USEPA (2013) framework. Although not all of the studies meet all of the 13 criteria listed in USEPA's (2013) framework, Budinsky et al. (2008) meets nearly all of the criteria, and the rest of the studies meet 5 or more of USEPA's 13 criteria. Integral's evaluation of the literature relative to USEPA's (2013) framework is provided in Attachment A.

Allowance for the use of an RBA for dioxins and furans, even though not every criterion is met by all supporting studies, is consistent with the approach that USEPA used to derive its default RBA value for arsenic (USEPA 2010b, 2012a, 2012b). Although it is USEPA's preference that site-specific bioavailability studies be used for site-specific risk assessment, USEPA has, nevertheless, developed a default value for arsenic that can be used when site-specific data are not available or feasible. The default RBA for arsenic was derived by USEPA using a very different methodology than that outlined in USEPA's (2013) framework. Despite several confounding factors in the data describing arsenic bioavailability, USEPA combined the data from all studies, including different test animals, different chemical forms of arsenic, different dosing regimens, and different measurement endpoints, into a single dataset to derive its RBA factor. Once the data were combined, USEPA selected the 95th percentile of the resulting distribution of values as the default value, concluding that values for an arsenic RBA exceeding 60 percent were uncommon. USEPA acknowledged that the use of a national default value in place of a site-specific value contributes some uncertainty to risk estimates. However, USEPA has determined that the default value of 60 percent can be used because this RBA is an estimate that is not likely to be exceeded at most sites, and its use is preferable to over-estimation of risks that would result from the assumption that the RBA is 100 percent (USEPA 2012b).

[1] This is the absorption rate of TCDD from food by experimental animals reported by Fries and Marrow (1975; JECFA 2002).

The process and rationale supporting USEPA's selection of the arsenic RBA are similar to those supporting the RBA for lead. In the case of lead, data from multiple studies of different lead sources and different animal species were combined to develop USEPA's (2007) RBAs for lead. These RBAs are included in the IEUBK and Adult Lead Methodology models that are routinely used by USEPA and other risk assessors.

Our selection of an RBA of 0.50 for dioxins and furans, and its application in the baseline HHRA and the derivation of protective concentration levels (PCLs) for the SJRWP RI/FS, are technically well-founded, and consistent with USEPA's approach to selecting default RBAs for other chemicals.

Sincerely,

Jennifer Sampson
Senior Managing Scientist

Enclosure

Cc:
Philip Turner, USEPA
David Keith, Anchor QEA
David Moreira, McGinnes Industrial Maintenance Corp.
Philip Slowiak, International Paper Company

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ATTACHMENT A

INTRODUCTION

The U.S. Environmental Protection Agency (USEPA; 2010) provides a summary of nine papers from the peer-reviewed literature that are relevant to derivation of the relative bioavailability adjustment (RBA) factor used in the baseline human health risk assessment for the San Jacinto River Waste Pits remedial investigation and feasibility study, approved in May, 2013. In July, 2013, USEPA published a set of criteria to be met by studies used to support application of RBAs in risk assessment (USEPA 2013). A summary of all the literature reviewed by USEPA (2010) can be found in that document, and a copy of Table 1 from that document, which provides a list of the literature reviewed, is appended to this attachment as Exhibit 1. A discussion of this body of literature relative to USEPA's (2013) framework is presented below.

SUMMARY OF THE USEPA (2013) FRAMEWORK

USEPA's (2013) framework for developing RBA factors for dioxin in soil includes 13 minimum experimental design requirements for an assay to meet for it to provide a basis for the RBA factor to be used in risk assessment. These include the following (as presented by USEPA 2013):

1. Risk assessment requires that an estimate be derived of the relative bioavailability for polychlorinated dioxin and furan (PCDD/F) [polychlorinated dibenzo-*p*-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)] toxic equivalents (TEQ) in soil (RBA_{TEQ}).
2. Calculation of the RBA_{TEQ} requires quantification of the total TEQ external dose and total TEQ internal dose, as well as the excretion fraction for TEQ.
3. For noncancer risk assessment, it is necessary to have two RBA estimates: 1) RBA for TEQ in corn oil ($ABA_{TEQ,corn\ oil}/ABA_{TCDD,corn\ oil}$) where the ABA is the absolute bioavailability, and 2) estimate of the RBA for TEQ in soil ($ABA_{TEQ,soil}/ABA_{TEQ,corn\ oil}$).
4. For cancer risk assessment, two RBA estimates are needed. These include 1) estimate of RBA for TEQ in food ($ABA_{TEQ,food}/ABA_{TCDD,food}$), and 2) RBA for TEQ in soil ($ABA_{TEQsoil}/ABA_{TEQ,food}$).
5. There is no general consensus on the preferred animal model for estimating RBA for PCDD/PCDF as RBA assays have been conducted in rats and swine and have yielded different estimates of RBA_{TEQ}.

6a. External doses of TEQ should not exert overt systemic toxicity, and external doses should be well below the LD_{50} and preferably well below to LD_{01}.

6b. Multiple dose levels of TEQ should be administered to allow an evaluation of the dose-dependence of RBA.

6c. External doses of TEQ delivered in the test and reference materials must result in similar or overlapping ranges of internal doses of TEQ, in order to prevent different levels of induction of CYP450 and different elimination fractions of TEQ for the test and reference materials.

6d. There is no general consensus as to whether single doses or repeated doses should be administered. Regardless, a sufficient cumulative and non-toxic external dose must be delivered to allow quantification of the internal dose of the administered congeners that comprise ≥95 percent of the administered TEQ.

6e. The administered soil should be the <250 μm fraction.

7. Tissues selected for assay of congeners should provide reliable predictions of the TEQ body burden. There is no general consensus regarding which tissue would satisfy this requirement and it is likely to vary across animal species. Ideally, if whole body (GI tract excluded) is not analyzed for TEQ, selected tissues should include those that collectively contribute ≥50 percent of total body burden. At a minimum this should include liver and adipose.

8. The study design must provide statistical confidence limits on the estimate of the RBA and an evaluation of reproducibility of RBA estimates when the same test materials are assayed.

9. Study designs intended to estimate RBA of PCDD/PCDF in soils should include a characterization of the soil that includes a complete analysis of PCDD/PCDF congeners, as well as soil characteristics including, at a minimum, total solids, pH, total organic carbon and grain size distribution.

EVALUATION OF BUDINSKY ET AL. (2008) RELATIVE TO USEPA (2013)

The study by Budinsky et al. (2008) meets nearly all of USEPA's (2013) criteria. Budinsky et al. (2008) calculated RBAs for both swine and rats following administration of two types of soils (sieved to 250 μm) from two different sources (urban and floodplain) that contained differing TEQ concentrations of PCDD/PCDFs. Animals were dosed daily over a 30-day period and residuals of the five congeners that contributed the greatest fraction (greater than 85 percent in each soil sample) of the TEQ were measured in the soil, the administered dose, and in both the liver and adipose tissues. The only deficits of Budinsky et al. (2008) related to the criteria outlined in USEPA's (2013) framework are the following:

- Criterion 2 – Budinsky et al. (2008) measured both administered and internal doses but excretion/elimination was not measured. Rather, assumptions were made about these.
- Criterion 4 – Budinsky et al. (2008) did not provide an estimate of the RBA for food. Because noncancer hazards are the driver of risk management decision-making for dioxins and furans at the San Jacinto River Waste Pits site, this deficiency is not important.
- Criterion 6b – Multiple dose levels were administered but the soils in which they were administered were not identical in that they had different pH, organic carbon content, and grain size distributions. The TEQ in the urban soil was due primarily to dioxin congeners while the TEQ in the floodplain soil was due to furan congeners. This confounds any conclusions about dose-dependence of the RBA.
- Criterion 6c – In the rats of the Budinsky et al. (2008) study, the internal doses resulting from the test material differed from the internal doses resulting from the reference material (this was not the case for the swine). The authors speculated that this may have been because the rats ate less than expected (so their intake in soil was lower than anticipated). It may also have been because the bioavailability in the reference material was higher than expected, which can occur in freshly spiked soils that have not weathered, like those used for the reference material. This resulted in a greater internal dose in the reference animals (measured through rates of enzyme induction in the study and control animals) than in the animals exposed to the test material. This was, however, addressed with a follow-up study (Budinsky et al. 2008) to balance the dose levels. USEPA's Criterion 6c was met for the part of the experiment conducted with swine, although some congeners were not detectable in the swine tissues. RBA factors were calculated by Budinsky et al. (2008) and presented using both the detection limit and one-half the detection limit for those congeners.
- Criterion 8 – While no actual confidence intervals are provided around the RBAs, the standard deviation provides some insight into the variability in the estimates.

Based on their experimental data, Budinsky et al. (2008) reported separate RBAs for PCDD and PCDF TEQ. For swine, the RBA for the PCDD TEQ was reported to be 20 percent, while for rats the this value was reported to be 37 percent.

EVALUATION OF OTHER BIOAVAILABILITY STUDIES RELATIVE TO USEPA (2013)

Table 1 of USEPA's (2010) report (Exhibit 1) on bioavailability of dioxin provides a summary of the RBA studies of dioxins in soil. Nine studies are summarized, and six studies were selected by USEPA for estimating RBAs. Test species evaluated in these studies included rabbits, swine, rats, and guinea pigs. Integral evaluated each of the six

studies presented by USEPA (2010) against USEPA's (2013) framework, and found that the Budinsky et al. (2008) study met 11 of the 13 criteria outlined in USEPA's (2013) framework, and the remaining studies met 5 to 7 of those criteria. Among these studies, different types of soil and different dosing regimens were tested (which was also the case for the range of studies used by USEPA to develop the RBA for arsenic). In addition, some studies evaluated a mixture of congeners to address the bioavailability for an overall TEQ, while others only evaluated TCDD. Each of the studies used PCDDs/PCDFs aged in soils. Therefore, although not all papers could conform to the framework USEPA presented in 2013, the literature is consistent with several important criteria.

Budinsky et al. (2008) indicate that the RBAs for swine are substantially lower than the RBAs for rats. This may be an important consideration as USEPA currently recommends the use of a swine RBA assay to predict the lead RBA in human health risk assessments because swine are considered to provide a good physiological model for gastrointestinal absorption in children (USEPA 2007). The RBAs reported by Budinsky et al. (2008) include a mean value of 26 percent with a 95th percentile of 28 percent. It is important to note, however, that USEPA has not yet reached consensus on the most appropriate test species to be used in developing an RBA for dioxins and furans.

CONCLUSIONS

Integral's analysis of the primary literature and comparison of the relevant publications to the USEPA (2013) framework indicate that application of an RBA of 0.50 to the evaluation of potential human exposure to dioxins and furans following incidental ingestions of soils and sediments is appropriate. Although USEPA's framework was published after approval of the final HHRA and related documentation, our analysis finds that the evidence supporting the RBA selected for the HHRA is largely consistent with the USEPA (2013) framework. Therefore, both the results of the risk assessment and calculation of protective concentration levels for the San Jacinto River Waste Pits RI/FS are complete and final.

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Table 1. Summary of RBA Studies of Dioxins in Soil

Reference	Test Material	Species/Number	Methods	RBA
Bonaccorsi et al. 1984	Source: Seveso, Italy soil (200–400 mesh) TCDD Concentration: 81 ng/g (ppb)	Rabbit (Albino, male, 2.6±0.3 kg), 5–16/group	ID Metric: liver TCDD concentration TM Dose: 0.02 to 0.08 µg TCDD/day; 7 days TM Dosing: aqueous suspension, oral gavage, single dose RM Dosing: oral gavage in 50% ethanol, single dose	32%
Budinsky et al. 2008	Source: TM1: urban soil, Michigan (sieved to <250 µm) PCDD/F: 264 pg TEQ/g (ppt) Source: TM1: floodplain soil, Michigan (sieved to <250 µm) PCDD/F: 651 pg TEQ/g	Swine (*Sus scrofa*, sex and weight not given), 5/group	ID Metric: liver plus adipose PCDD/F content TM Dose: 122, 313 pg TEQ/kg-bw/day TM Dosing: 5 g soil placed in moistened feed, twice/day, 30 days RM Dosing: corn oil/acetone (99:1 v:v) in gelatin capsule, placed in moistened feed, twice/day, 30 days	23% (urban) 27% (flood plain) (TEQ-weighted)
Budinsky et al. 2008	Source: urban soil, Michigan (sieved to <250 µm) PCDD/F: 264 pg TEQ/g (ppt) Source: floodplain soil, Michigan (sieved to <250 µm) PCDD/F: 651 pg TEQ/g (ppt)	Rat (Sprague-Dawley, female, 250 g), 10/group	ID Metric: liver plus adipose PCDD/F content TM Dose: 577, 2100 pg TEQ/kg bw/day TM Dosing: 5% w/w soil-feed mixture, 30 days RM Dosing: corn oil/acetone (99:1, v:v), oral gavage, 30 days	37% (urban) 66% (flood plain) (TEQ-weighted)
Finley et al. 2009	Source: Operating U.S. industrial facility (sieved to <250 µm) PCDD/F Concentrations: TM1: 15.0 ng TEQ/g soil TM2: 45.0 ng TEQ/g soil TM3: 36.8 ng TEQ/g soil TM4: 2.8 ng TEQ/g soil TM5: 0.53 ng TEQ/g soil (ppb)	Rat (Sprague-Dawley, female, 251–321 g), 6/group	ID Metric: liver PCDD/F content TM Dosing: aqueous suspension, oral gavage, single dose TM Dose: TM1: 30,000 pg TEQ/kg bw/day TM2: 90,200 pg TEQ/kg bw/day TM3: 590 pg TEQ/kg bw/day TM4: 560 pg TEQ/kg bw/day TM5: 290 pg TEQ/kg bw/day RM Dosing: corn oil, oral gavage, single dose	TM1: 16.7% TM2: 48.4% TM3: 37.7% TM4: 46.5% TM5: 33.3% (TEQ Weighted)

Table 1. Summary of RBA Studies of Dioxins in Soil

Reference	Test Material	Species/Number	Methods	RBA
Lucier et al. 1986	Source: Minker/Stout site, Missouri (sieved 60 gauge) TCDD: 880 ng/g (ppb)	Rat (Sprague-Dawley, female), 6/group	ID Metric: liver TCDD concentration TM Dose: 1.1, 5.5 µg TCDD/kg-bw TM Dosing: aqueous suspension, oral gavage, single dose RM Dosing: corn oil, oral gavage, single dose	22% (1.1 µg/kg) 45% (5.5 mg/kg)
McConnell et al. 1984	Source: Times Beach site, Missouri (sieved 60 gauge) TCDD: 770 ng/g (ppb) Source: Minker/Stout, Missouri (sieved 60 gauge) TCDD: 880 ng/g (ppb)	Guinea pig (Hartley, male, 2.5 weeks old), 6/group	ID Metric: liver TCDD concentration TM Dosing: aqueous suspension, oral gavage, single dose TM Dose: 1–10 µg TCDD/kg bw/day RM Dosing: corn oil, oral gavage, single dose	8% (Times Beach, 3.8 µg/kg, 20% lethality) 11% (Minker Stout, 3.3 µg/kg, 33% lethality)
Shu et al. 1988	Source: Times Beach soil, Missouri (sieved through 40 mesh screen) TCDD: 1.9 to 723 ng/g (ppb)	Rat (Sprague-Dawley derived, 180 to 250 g), 4/group	ID Metric: liver TCDD concentration TM Dosing: aqueous suspension, oral gavage, single dose TM Dose: 3.2, 7.0, 40, 37, 175,1450 ng TCDD/kg RM Dosing: corn oil, oral gavage, single dose	44% (3.2 ng/kg) 49% (7 ng/kg) 38% (40 ng/kg) 43% (37 ng/kg) 45% (175 ng/kg) 37% (1450 ng/kg)
Umbreit et al. 1986	Source: Manufacturing plant in Newark, NJ TCDD: ~2,300 ng/g (ppb) Source: Salvage yard contaminated with chemical stills, Newark NJ TCDD: NR	Guinea pig (males and females; strain, weight and age not given, 8/group)	ID Metric: liver TCDD concentration TM Dose: 3, 6, 12 µg TCDD/kg TM Dosing: aqueous suspension, oral gavage, single dose RM Dosing: corn oil/acetone (9:1, v:v), oral gavage, single dose	<1% (manufacturing site, 12 µg/kg, relative to spiked soil) 24% (salvage yard, 0.32 µg/kg, relative to spiked soil)
Wendling et al. 1989	Source: Times Beach, Michigan TCDD: 510 ng/g (ppb) Source: Newark, NJ TCDD: 1,400 ng/g (ppb)	Guinea pig (200 g), 2/group	ID Metric: liver TCDD concentration TM Dosing: 10% gum acacia, oral gavage, single dose TM Dose: 3–10 µg TCDD/kg RM Dosing: 10% gum acacia, oral gavage, single dose	7%, 30% (Times Beach, 3 or 10 µg/kg) 2.0, 1.6% (Newark, 5 or 10 µg/kg)

Table 1. Summary of RBA Studies of Dioxins in Soil

Reference	Test Material	Species/Number	Methods	RBA
Wittsiepe et al. 2007	Source: Surface soil near Hamburg, Germany PCDD/F: 5.3 ng TEQ/g (ppb)	Swine (Goettingen mini-pig, males and females, 6975 g), 4/group	ID Metric: PCDD/F content of tissues (adipose, blood, brain, liver, muscle) TM Dosing: 0.5 g soil/kg bw/day placed in moistened feed TM Dose: 2.3 ng TEQ/kg bw/day, 28 days RM Dosing: hexane/acetone (1:1, v:v), placed in moistened feed, 28 days	28.4±9.9 (SD) (total congener)

ID, internal dose; NR, not reported; PCDD/F, polychlorinated dibenzo-p-dioxin/dibenzo furan; ppb, parts per billion; pg, picogram; ppt, parts per trillion; RM, reference material; SD, standard deviation; TCDD, tetrachloro-p-dibenzodioxin; TEQ, toxic equivalent; TM, test material; µm, micron